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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/586,109

10/31/2006

Eric Allain

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EXAMINER

PAK, YONG D

ART UNIT

PAPER NUMBER

1652

NOTIFICATION DATE

DELIVERY MODE

06/01/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary	Application No. 10/586,109	Applicant(s) ALLAIN ET AL.	
	Examiner YONG D. PAK	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/2/08, 8/26/08, 6/11/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 of PCT/US05/01147.

The preliminary amendment filed on July 14, 2006, amending claims 2-15, 17, and 19, canceling claims 16 and 20-33, has been entered. However, Examiner notes that according Rule 126, claim 24 was renumbered as claim 34.

The amendment filed on April 6, 2009 canceling claims 1-15, 17-19, and 33 and adding claims 34-50 has been entered. However, Examiner notes that it appears that applicants have meant to cancel claims 1-15, 17-19, and **34**. Therefore, according Rule 126, claims 34-50 have been renumbered as claims 35-51. It is urged that applicants reflect this renumbering in next amendment.

Claims 35-51 are pending and are under consideration.

Election/Restrictions

Applicant's election with traverse of the species hybrid enzyme comprising an *Aspergillus kawachi* alpha-amylase carbohydrate binding module (CBM) in the reply filed on April 6, 2009 is acknowledged. The traversal is on the ground(s) that there would not be a serious burden on the examiner if the restriction were not required. This is not found persuasive because lack of unity is not dependent on whether a search is burdensome or not.

The requirement is still deemed proper and is therefore made FINAL.

Claim for Domestic Priority

Applicants' claim for domestic priority under 35 USC 119(e) to US provisional applications 60/537,071, filed 1/16/2004, and 60/636,013, filed 12/14/2004, are acknowledged.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on October 2, 2008, August 26, 2008, and June 11, 2007 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, pages 12 and 15 for example. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41 and 47 recite the phrase “derived from”. The metes and bounds of this phrase are not clear to the Examiner. Literally, while the term “derived” means “to isolate from or obtain from a source”, the above term could also mean “to arrive at by reasoning i.e., to deduce or infer” or also as “to produce or obtain from another substance”. Therefore, it is not clear to the Examiner either from the specification or from the claims as to what applicants mean by the above phrase. It is not clear to the Examiner whether the glucoamylase “derived from *Athelia rolfsii*” encompasses a single specific enzyme (SEQ ID NO:2), as in isolated from *Athelia rolfsii*, or whether it encompasses recombinants, variants and mutants of glucoamylase from any other source and labeled as a glucoamylase “derived from *Athelia rolfsii*”. Similarly, is not clear to the Examiner whether the CBM “derived from *Aspergillus kawachii*” encompasses specific amino acid sequences obtained from the alpha-amylase isolated from *Aspergillus kawachii*, or whether it encompasses any amino acid sequences that bind carbohydrates and labeled as a CBM “derived from *Aspergillus kawachii*”. As applicants have not provided a definition for the above phrase, Examiner has interpreted the claims broadly to mean that a glucoamylase “derived from *Athelia rolfsii*” encompasses polypeptides which are recombinants, variants or mutants of any glucoamylase and that a CBM “derived from *Aspergillus kawachii*” encompasses

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polypeptides which are recombinants, variants or mutants of any alphy-amylases that bind carbohydrates. Examiner has given the same interpretation while considering the claims for all other rejections. The rejection can be overcome by amending the phrase to recite "wherein the glucoamylase is isolated from *Athelia rolfsii*" or "wherein the CBM derived from *Aspergillus kawachii* alpha-amylase has the amino acid sequence of SEQ ID NO:13".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-49 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 35-49 and 51 are drawn to a method producing a fermentation product from milled starch containing material by saccharifying said milled starch-containing material with a glucoamylase. It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." In this case, the examiner has broadly interpreted the claims to encompass a method of producing any product by fermentation. Therefore, the claims are drawn to a method of

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producing a genus of fermentation products having unknown structure by saccharifying said milled starch-containing material with a glucoamylase. .

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, (or) chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

The claims are drawn to a method of producing a genus of fermentation products having unknown structure by using a glucoamylase. There is insufficient descriptive support for the genus of these fermentation products. The specification does not disclose even a representative number of each of the above and/or structurally

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identifiable characteristics of the genus. The specification only describes a method of producing ethanol by saccharifying milled starch-containing material with a glucoamylase. This species of ethanol is not enough and does not constitute a representative number of all the species to describe the whole genus and there is no evidence on the record of the relationship between the structure of ethanol and the structure of any or all fermentation products. Therefore, the specification fails to describe the species produced by the claimed method.

Given this lack of additional representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 35-49 and 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing ethanol by saccharifying milled starch-containing material with a glucoamylase, does not reasonably provide enablement for a method of producing any fermentation product by saccharifying milled starch-containing material with a glucoamylase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

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nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claims 35-49 and 51 are drawn to a method producing a fermentation product from milled starch containing material by saccharifying said milled starch-containing material with a glucoamylase.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." In this case, It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." In this case, the examiner has broadly interpreted the claims to encompass a method of producing any product by fermentation. Therefore, the claims are drawn to a method of producing any products having unknown structure by saccharifying said milled starch-containing material with a glucoamylase. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

The scope of the claim is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of fermentation products encompassed by the claims. The claims encompass a method of producing a wide variety of fermentation products. Since the structure of the chemical determines which chemical reactions, enzymes, substrates, and specific microorganisms are needed, predictability of which chemicals can be produced requires a knowledge of and guidance.

However, in this case the disclosure is limited to a method of producing ethanol by saccharifying milled starch-containing material with a glucoamylase, but provides no guidance with regard to producing any or all fermentation products. It would require undue experimentation of the skilled artisan to make any fermentation products. In view of the great breadth of the claim, amount of experimentation required to make any fermentation products, the lack of guidance, working examples, and/or unpredictability of the art in predicting function of chemical from its chemical structure, the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to make the full scope of the fermentation products encompassed by the claims.

The specification does not support the broad scope of the claims which encompass a method of making any or all fermentation product by saccharifying a milled starch-containing material with a glucoamylase because the specification does not establish: (A) a universal method to make any or all compounds fermentation products by saccharifying milled starch-containing material; (B) a rational and

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predictable scheme for making any fermentation products; and (C) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a method of producing any products having unknown structure by saccharifying said milled starch-containing material with a glucoamylase. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of NADPH oxidase inhibitors that inhibit angiogenesis in any tissue is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 35-40, 42- 44, and 50-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagasaka et al.

Claims 35-40, 42-44, and 50-51 are drawn to a method of producing ethanol from milled starch-containing material obtained from whole grain by simultaneous saccharification and fermentation, wherein said starch-containing material is saccharified with a glucoamylase having at least 70-97% sequence identity to SEQ ID NO:2 and derived from *Athelia rolfsii* at a temperature below the gelatinization temperature of said starch-containing material and the sugar concentration is kept at a level below 3 wt %.

Nagasaka et al. (Appl Microbiol Biotechnol. 1995 Dec;44(3-4):451-8 – form PTO-892) discloses a method of producing ethanol from milled starch-containing material obtained from whole grain by simultaneous saccharification and fermentation, wherein said starch-containing material is saccharified with a glucoamylase having at least 80-

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97% sequence identity to SEQ ID NO:2 and the sugar concentration is kept at a level below 3 wt % (page 451, 453 and Figure 2 on page 454). The glucoamylase used by Nagasaka et al. is isolated from *Corticium rolfsii*, which is a synonym for *Athelia rolfsii* (see attachment "Athelia rolfsii"). The saccharification of "cooked soluble starch" is carried out at 30°C (page 453). Therefore, the saccharification of Nagasaka et al. occurs at a temperature below the gelatinization temperature since gelatinization resulting in "cooked soluble starch" occurs above 30°C. Therefore, the reference of Nagasaka et al. anticipates claims 35-40, 42- 44, and 50-51.

Claims 35-40, 42, 44-47, and 49-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Borchert et al.

Claims 35-40, 42, 44-47, and 49-51 are drawn to a method of producing ethanol from milled starch-containing material obtained from whole grain by simultaneous saccharification and fermentation, wherein said starch-containing material is saccharified with a glucoamylase having at least 70-97% sequence identity to SEQ ID NO:2 and derived from *Athelia rolfsii* at a temperature below the gelatinization temperature of said starch-containing material and liquefied with a hybrid alpha-amylase comprising a catalytic domain and a carbohydrate binding domain derived from *Aspergillus kawachii*.

Borchert et al. (US 7,129,069 and US 7,312,055— form PTO-892) discloses a method of producing ethanol from milled starch-containing material obtained from whole grain by simultaneous saccharification and fermentation, wherein said starch-containing

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material is saccharified with a glucoamylase isolated from *Corticium rolfsii* AHU 9627 (Column 7, lines 30-67, Column 14, line 65 through Column 17, line 67 of U. S. Patent No. 7,129,069 and Column 7, line 34 through Column 8, line 5, and Column 14, line 21 through Column 17, line 67 of US 7,312,055) which is at least 70-97% identical to the glucoamylase of SEQ ID NO:2 of the instant invention (see Nagasaka et al., on page 454) at a temperature below the initial gelatinization. Therefore, the references of Borchert et al. anticipates claims 35-40, 42, 44-47, and 49-51.

The applied reference has a common inventor (Eric Allain) and assignee (Novozymes) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 35-40 and 42-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veit et al. and Nagasaka et al.

Claims 35-40 and 42-51 are drawn to a method of producing and recovering ethanol from milled starch-containing material obtained from whole grain by simultaneous saccharification and fermentation, wherein said starch-containing material is saccharified with a glucoamylase having at least 80-97% sequence identity to SEQ ID NO:2 and derived from *Athelia rolfsii* at a temperature below the gelatinization temperature of said starch-containing material, the sugar concentration is kept at a level below 3 wt %, and said method uses a fungal acid protease and a hybrid enzyme comprising an alpha-amylase catalytic domain (CD) and a carbohydrate-binding module (CBM) derived from *Aspergillus kawachii* alpha-amylase. Examiner notes that CBM “derived from *Aspergillus kawachii*” has been broadly interpreted as polypeptides which are recombinants, variants or mutants of any alphy-amylases that bind carbohydrates (see the rejection of the prhase under 35 USC 112, 2nd above).

Veit et al. (US 7,244,597 B2 or WO 02/38787 A2 - form PTO-892) discloses a method of producing and recovering ethanol by (1) milling a whole grain, (2) liquefaction of the milled starch-containing material with an alpha-amylase hybrid, and (3) simultaneous saccharification and fermentation of the product from step (2) (Column 1, lines 48-62 of US 7,244,597 or pages 1-2 of WO 02/38787 A2). Step (2) of Veit et al. utilizes alpha-amylase hybrid comprising 445 C-terminal amino acid residue of the *Bacillus licheniformis* alpha-amylase and the 37 N-terminal amino acid residue of the alpha-amylase derived from *Bacillus amyloliquefacien* (Column 9, lines 4-8 of US 7,244,597 or page 11 of WO 02/38787 A2). Since the hybrid used by Veit et al. functions as an alpha-amylase, the structure of the CMB is not recited in the claims and the specification does not define the phrase "derived from" but describes CBM having at least 50-99% sequence identity to the CBM domain of the alpha-amylase of *Aspergillus kawachii* (EMBL:#AB008370 or SEQ ID NO:31 on page 13 of the specification), Examiner takes the position that the hybrid alpha-amylase used by Veit et al. comprises a CD domain and a CBM domain, wherein the CBM domain is "derived from" *Aspergillus kawachii*. Step (3) of Veit et al. employs a fungal acid protease (Column 12, lines 9-37 of US 7,244,597 or page 15 of WO 02/38787 A2) and is carried out at a temperature below the initial gelatinization temperature (Column 5, lines 18-67 of US 7,244,597 or pages 6-7 of WO 02/38787 A2).

The difference between the reference of Veit et al. and the instant invention is that the reference of Veit et al. does not use a glucoamylase having at least 70-97% sequence identity to SEQ ID NO:2 or a glucoamylase having at least 70% sequence

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identity to SEQ ID NO:2 and derived from *Athelia rolfsii*, wherein the sugar concentration is kept at a level below 3 wt %. However, Veit et al. discloses that the preferred glucoamylase is of any fungal origin (Column 11, lines 38-67 of US 7,244,597 or page 14 of WO 02/38787 A2).

Nagasaka et al. (Appl Microbiol Biotechnol. 1995 Dec;44(3-4):451-8 – form PTO-892) discloses a method of producing ethanol from milled starch-containing material obtained from whole grain by simultaneous saccharification and fermentation, wherein said starch-containing material is saccharified with a fungal glucoamylase having at least 80-97% sequence identity to SEQ ID NO:2 and the sugar concentration is kept at a level below 3 wt % (page 451, 453 and Figure 2 on page 454). The glucoamylase used by Nagasaka et al. is isolated from *Corticium rolfsii*, which is a synonym for *Athelia rolfsii*, as discussed above. Nagasaka et al. teaches the cDNA encoding the above glucoamylase and that the enzyme has a high degree of starch degrading activity compared to other glucoamylases ((page 451 and Figure 2 on page 454).

Therefore, combining the teachings of Veit et al. and Nagasaka et al., it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use the glucoamylase of Nagasaka et al. in the method of Veit et al. One of ordinary skill in the art at the time the invention was made would have been motivated to use the glucoamylase of Nagasaka et al. since the glucoamylase of Nagasaka et al. is of fungal origin, gene encoding the enzyme of Nagasaka et al. is disclosed and said enzyme can be produced in large, highly-purified quantities, and the

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glucoamylase of Nagasaka et al. has a high starch degrading activity compared to other glucoamylases.

One of ordinary skill in the art would have had a reasonable expectation of success since Veit et al. teaches a method of producing and recovering ethanol by liquefying a milled starch using a hybrid alpha-amylase, simultaneous saccharification and fermentation with a fungal glucoamylase and a fermenting microorganism and Nagasaka et al. discloses a fungal glucoamylase and cDNA encoding said protein.

Therefore, the above references render claims 35-40 and 42-51 *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-40, 42, 47, and 49-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U. S.

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Patent No. 7,129,069 and US Patent No. 7,312,055. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: Claims 35-40, 42, 44-47, and 49-51 of the instant application and claims 15-21 of U. S. Patent No. 7,129,069 and 19-21 of U. S. Patent No. 7,312,055 are all directed to a method of producing ethanol from starch using a fermenting organism. Claims 35-40, 42, 44-47, and 49-51 of the instant application are drawn to a method of producing ethanol from starch by liquefaction using a hybrid alpha-amylase comprising a catalytic domain and a carbohydrate binding domain derived from *Aspergillus kawachii* and simultaneous fermentation and saccharification using a glucoamylase having at least 70-97% sequence identity to SEQ ID NO:2 of the instant application. Claims 15-21 of U. S. Patent No. 7,129,069 and 19-21 of U. S. Patent No. 7,312,055 are drawn to a method producing ethanol from starching comprising liquefaction using a hybrid alpha-amylase comprising a catalytic domain and a carbohydrate binding domain derived from *Aspergillus kawachii*. The specification of the reference patent supports simultaneous fermentation and saccharification using a glucoamylase isolated from *Athelia rolfsii* AHU 9627 (Column 7, lines 30-67, Column 14, line 65 through Column 17, line 67 of U. S. Patent No. 7,129,069 and Column 7, line 34 through Column 8, line 5, and Column 14, line 21 through Column 17, line 67), which is at least 70-97% identical to the glucoamylase of SEQ ID NO:2 of the instant invention (see Nagasaka et al., on page 454) that would anticipate claims 15-21 of U. S. Patent No. 7,129,069 and 19-21 of U. S. Patent No. 7,312,055. Claims 35-40, 42, 44-47, and 49-51 of the instant application cannot be

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considered patentably distinct over claims 15-21 of U. S. Patent No. 7,129,069 and 19-21 of U. S. Patent No. 7,312,055 when there is specifically recited embodiment that would anticipate claims 35-40, 42, 44-47, and 49-51 of the instant application.

Alternatively, claims 35-40, 42, 44-47, and 49-51 of the instant application cannot be considered patentably distinct over claims 15-21 of U. S. Patent No. 7,129,069 and 19-21 of U. S. Patent No. 7,312,055 because it would have been obvious to one having ordinary skill in the art to modify the claims of the reference patent by selecting a specifically disclosed embodiment that supports those claimed, Simultaneous fermentation and saccharification using a glucoamylase isolated from *Athelia rolfsii* AHU 9627. One of ordinary skill in the art would have been motivated to do this because the embodiments claimed in the instant claims are disclosed as being a preferred embodiment within claims 15-21 of U. S. Patent No. 7,129,069 and 19-21 of U. S. Patent No. 7,312,055. Therefore, the conflicting claims are not patentably distinct from each other.

Conclusion

Claim 35-51 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935.

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The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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/Yong D Pak/
Primary Examiner, Art Unit 1652